LABEL IN PART: "Thiede's Stretch-To-Health Head Harness Spine Normalizer Patent Applied For Serial No. D–27615 Manufactured and designed by Cliff Thiede 250 Shelley Street Phone 4293 Idaho Falls, Idaho."

ACCOMPANYING LABELING: Pamphlets entitled "Well I'll Be Hanged! Stretch Your Spine For Health."

RESULTS OF INVESTIGATION: The device consisted of chains, a doorway hanger, and a head harness for suspending the head.

LIBELED: 6–12–57, Dist. Utah.

CHARGE: 502 (a)—when shipped, the designation "Thiede's Stretch-To-Health Head Harness" and the labeling of the devices contained false and misleading representations that the devices were an adequate and effective treatment for normalizing the spine muscles, spasm, osteoarthritis, disc degeneration, herniated disc or disc protrusion, neuritis, headaches (migraine), nervous disorders, premature aging, poor circulation, poor elimination of waste material, decreased body functions, chronic strain, thinning of the vertebral discs, back and neck troubles, serious injury and malfunctioning of the organs of the body, and promoting and maintaining health; and 502 (f) (1)—the devices should be restricted to sale only on prescription since they were devices, which because of any potentiality for harmful effect, or the method of their use, or the collateral measures necessary to their use, were not safe except under the supervision of a practitioner licensed by law to direct the use of such devices, and hence for which "adequate directions for use" could not be prepared; and their labels failed to bear the statement "Caution: Federal law restricts this device to sale by or on the order of a ————, (the blank to be filled in by the professional designation of a properly licensed member of a professional group)."

DISPOSITION: 8–23–57. Consent—claimed by Clifford Thiede and relabeled.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

5408. Digitoxin powder and digitoxin tablets. (F. D. C. No. 40157. S. Nos. 60–319/20 M.)

QUANTITY: 1 25-gram btl. of *digitoxin powder* and 69 1,000-tablet btls. of *digitoxin tablets* at Detroit, Mich.

SHIPPED: 11–27–56, from New York, N. Y., by European Chemical Co., Inc.

LABEL IN PART: (Btl.) "Digitoxin U. S. P. For Manufacturing Use Only * * * Net 25 gms. European Chemical Co., Inc., New York, N. Y." and "Digitoxin, Mallard, 1000 tablets, White Round * * * Mallard, Inc., Detroit, Mich."

RESULTS OF INVESTIGATION: The *digitoxin tablets* were prepared by the consignee using a portion of the bulk *digitoxin powder*.

Examination showed that the powder contained not more than 83.5 percent of digitoxin and that the tablets contained not more than 0.162 milligrams of digitoxin per tablet.

LIBELED: 4–23–57, E. Dist. Mich.

CHARGE: 501 (b)—the *digitoxin powder* and the *digitoxin tablets* purported to be a drug, "Digitoxin," the name of which is recognized in the United States Pharmacopeia, an official compendium; and, when the powder was shipped and while the tablets were held for sale, the strength of the articles differed

*See also Nos. 5401, 5402.

from, and their quality fell below, the official standard since the articles contained less than 90 percent of the labeled amount of digitoxin, the minimum permitted by the standard.

DISPOSITION: 6–25–57. Default—destruction.

5409. Digitoxin powder and digitoxin tablets. (F. D. C. No. 40117. S. Nos. 42–964/5 M.)

QUANTITY: 1 24-gram btl., 14 1,000-tablet btls., and 4 100-tablet btls. at Peoria, Ill.

SHIPPED: Between 12–1–55 and 1–18–57, from Newark, N. J., by Chemo Puro Mfg. Corp.

LABEL IN PART: (Btl.) "Digitoxin U. S. P. * * * For Manufacturing, Processing or Repacking" and "Digitoxin Tablets Each tablet contains Digitoxin. . . . 0.22 mg. (1/300 gr.)."

RESULTS OF INVESTIGATION: The above tablets were prepared by the consignee from the bulk powder shipped on or about 12–1–55.

Examination showed that the powder contained not more than 85.8 percent of digitoxin and that the tablets contained not more than 70.2 percent of digitoxin when assayed by the methods specified in the United States Pharmacopeia. The Pharmacopeia requires that the assay result be not less than 90 percent of digitoxin.

LIBELED: 4–4–57, S. Dist. Ill.

CHARGE: 501 (b)—the article, when shipped and while held for sale, purported to be a drug, "Digitoxin," the name of which is recognized in the United States Pharmacopeia, an official compendium, and the strength of the article differed from, and its quality fell below, the standard set forth in such compendium.

DISPOSITION: 5–13–57. Default—destruction.

5410. Digitoxin tablets. (F. D. C. No. 40173. S. Nos. 62–829/31 M.)

QUANTITY: 75,600 tablets packed in btls. of 100, 500, and 1,000 tablets; 154,100 tablets in a fiber drum and in bottles; and 97,000 tablets in a fiber drum, at Brooklyn, N. Y.

SHIPPED: On or about 5–4–55, from Paris, France.

LABEL IN PART: (Drum) "Digitoxin 0.1 mg. [or "0.2 mg."]"; (btl.) "Digitoxin Tablets U. S. P. 0.1 mg. [or "0.2 mg."]."

RESULTS OF INVESTIGATION: A quantity of digitoxin powder was shipped as described above; and, upon arrival at Brooklyn, N. Y., it was used to prepare the *digitoxin tablets.*

Examination showed that the tablets contained digitoxin in amounts of not more than (75,600-tablet lot) 82.4 percent of the declared amount, (154,100-tablet lot) 84.2 percent of the declared amount, and (97,000-tablet lot) 76.2 percent of the declared amount.

LIBELED: 5–1–57, E. Dist. N. Y.

CHARGE: 501 (b)—while held for sale, the strength of the article differed from, and its quality fell below, the standard for digitoxin set forth in the United States Pharmacopeia since the article contained less than 90 percent of the labeled amount of digitoxin.

DISPOSITION: 6–4–57. Default—destruction.